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Dockets Management Branch
Food and Drug Administration (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

July 9, 2004

Re: Docket No. 03P-0029 – Proposed Rule: Use of Ozone-Depleting Substances; Removal of Essential-Use Designations

Dear Sir or Madam:

GlaxoSmithKline (GSK) hereby informs FDA and the public that it is now proceeding to expand the production capacity of its facility in Zebulon, North Carolina to produce 30 million Ventolin HFA metered-dose inhalers (MDIs) annually. GSK is undertaking this expansion without awaiting further developments in the above-referenced rulemaking. GSK can have this production capacity in place and operable by December 31, 2005. When FDA publishes its final rule on CFC albuterol non-essentiality, which FDA has previously stated that it would do by March 2005, GSK may re-evaluate the timing for completing its expansion if the effective date for CFC albuterol non-essentiality is substantially beyond December 31, 2005.

In its presentation to FDA's Pulmonary and Allergy Drug Advisory Committee (PADAC) on June 10, 2004, GSK outlined the steps that would be required to expand the production capacity at its Zebulon facility. In our presentation, GSK indicated that up to 18 months might be needed to expand production capacity at Zebulon, although we did not indicate when the company would start the expansion. Now, having heard the discussion at the PADAC hearing, and having studied FDA's June 16, 2004 Notice of Proposed Rulemaking on CFC albuterol MDI non-essentiality, GSK more fully appreciates how FDA's decision-making can be assisted by firm, non-contingent commitments on production capacity from the manufacturers of HFA albuterol MDIs. We are making such a commitment now.

This letter therefore updates and revises GSK's previous statements on production capacity made in our letters to this docket of July 2, 2003 and March 5, 2004, and our statement to PADAC on June 10, 2004.

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GSK hopes that this information will assist FDA in its decision-making on albuterol MDI essentiality. If you have any questions or need additional information, please do not hesitate to contact me. Also, please note that GSK intends to file comments on other issues raised by the Proposed Rule in the near future.

Sincerely,

Jonathan Box
Senior Vice President
New Product and Global Supply